K003920

JUN 1 5 2001

510(k)
Summary of Safety and Effectiveness

Submitter: Cordis Corporation, a Johnson & Johnson Company
7 Powderhorn Drive
Warren, New Jersey 07059

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Date Prepared: December 18, 2000

Trade Name: Cordis M3 PTA Dilatation Catheter

Common Name: Percutaneous Transluminal Angioplasty (PTA) Balloon Catheter

Classification Name: (unclassified; FDA product code LIT)

Device Classification: Class II

Summary of Substantial Equivalence:
The design, materials, specifications, performance, packaging and intended use featured with the Cordis M3 PTA Dilatation Catheter are substantially equivalent to those featured among predicate devices such as the Cordis Opta LP and Slalom PTA catheters (ref. 510(k) #K971448, #K981407, and #K003159) and the Guidant Viatrac RX PTA catheters (ref. 510(k) K983055, K993639 and K000101).

In short, the subject M3 PTA Dilatation Catheter represents a line extension to the predicate Cordis PTA catheters that introduces a "rapid exchange" distal catheter design.

Device Description:
The M3 PTA Dilatation Catheter has an integrated shaft system and a balloon near the distal tip. The shaft has a combination of single lumen and dual lumen tubing. One lumen is used for inflation of the balloon with contrast medium. The second lumen, located only in the distal shaft, permits the use of a .014" diameter guidewire to facilitate the advancement of the catheter to and through the stenosis to be dilated. The catheter shaft has a distal port (hole) near the distal end that accesses the guidewire lumen. The guidewire lumen begins at the distal port and ends at the distal tip. This "rapid exchange" design allows insertion and removal of the catheter without extension of the guidewire.

The balloon has radiopaque marker(s) to aid in positioning the balloon within the stenosis, and is designed to provide an expandable segment of known diameter and length at a specific pressure.

The design of this catheter does not incorporate a lumen for distal dye injections or distal pressure measurements.

A flushing needle accessory is also provided with the device for flushing the catheter's inner guidewire lumen prior to use.

The M3 PTA Dilatation Catheter is provided sterile and is intended for single use only.

Intended Use:
The M3 PTA Dilatation catheter is intended:

a. To dilate stenosis in the peripheral arteries (iliac, femoral, ilio-femoral, popliteal, infra popliteal, renal arteries) or for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

b. For post-stent dilatation of the **PALMAZ™** Corinthian™ IQ PQ184B stent implanted in vessels ranging from 5.0 mm to 7.0 mm in diameter.

Technological Characteristics:
The subject M3 PTA Dilatation Catheter incorporates substantially equivalent indications for use, design, and dimensional and performance specifications as those found with the aforementioned predicate devices. The balloon is provided in a range of expanded diameters from 5.0 to 7.0 mm and in a length of 20mm. The device features a useable catheter length of 80cm.

Performance Data:

The safety and effectiveness of the Cordis M3 PTA Dilatation Catheter have been demonstrated via data collected from non-clinical tests and analyses, which addressed, among other considerations, the following:

- Biocompatibility
- Balloon minimum burst strength
- Balloon compliance (distensibility)
- Balloon inflation/deflation performance
- Balloon fatigue (repeated balloon inflation) endurance
- Bond strengths
- Catheter diameter and balloon profile
- Device preparation
- Catheter body minimum burst strength

A statement of substantial equivalence to another product is required by 21 CFR 807.87 and relates only to whether the present product can be marketed without prior reclassification or clinical approval. The present submission is therefore not related to the coverage of any patent and is not to be interpreted as an admission or used as evidence in a patent infringement lawsuit. As the commissioner of the stated, "A determination of substantial equivalence under the Federal Food, Drug and Cosmetic Act related to the fact that the product can be lawfully marketed without pre-market approval or reclassification. This determination is not intended to have any bearing whatsoever on the resolution of patent infringement suits." 42 Federal Register 42, 50 et seq. (1977).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Cordis Corporation,
a Johnson & Johnson Company
c/o Mr. Chuck Ryan
Manager, Regulatory Affairs
7 Powderhorn Drive
Warren, N.J. 07059

Re: K003920
Trade Name: CORDIS M3 PTA Dilatation Catheter
Regulation Number: 870.1250
Regulation Class: II (two)
Product Code: DQY and LIT
Dated: December 29, 2001
Received: January 02, 2001

Dear Mr. Ryan:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510 (k) Number: **K003920**

Device Name: **Cordis M3 PTA Dilatation Catheter**

Indications For Use:

The **Cordis M3 PTA Dilatation catheter** is intended:

a. To dilate stenosis in the peripheral arteries (iliac, femoral, ilio-femoral, popliteal, infra popliteal, renal arteries) or for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

b. For post-stent dilatation of the **PALMAZ® CORINTHIAN™** IQ PQ184B stent implanted in vessels ranging from 5.0 mm to 7.0 mm in diameter.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Cardiovascular, Respiratory and Neurological Devices

510(k) Number **K003920**